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On January 4, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: Sara B. McPeak  
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PATENT  
Attorney Docket No.: 16528A-038900US  
Client Reference No.: 2097

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Reidhaar-Olson, John F.

Application No.: 09/489,220

Filed: January 21, 2000

For: TOXICANT-INDUCED  
DIFFERENTIAL GENE EXPRESSION

Examiner: Lu, Frank

Art Unit: 1655

**AMENDMENT**

*C/8  
1/17/01  
1/11/01*

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Office Action mailed October 4, 2000, please amend the above-identified application as follows:

**IN THE SPECIFICATION:**

~~At page 2, line 23, delete the phrase "EST (AA03428)". At line 26, replace "Glutathione-S-transferase like" with --EST (AA441895)--.~~

~~At page 32, line 16, replace "48" with --47--.~~

~~At page 33, in Table 1, in the heading entitled "Name", please move the number 1 so it appears as a subscripted 1 at the end of the word "Name". Please delete the entire line that begins with the GenBank Accession Number AA034268. At the end of the table, after the~~

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entry for AI310515, please insert in the first column the phrase --AA805555--, and in the second column insert the word ~~EST~~.

At page ~~71~~, line 15, please replace "no" with --not--.

IN THE CLAIMS:

Please amend the claims as follows:

1. (Twice Amended) A method [of expression profiling] for detecting a  
2 toxic response, comprising:  
3 (a) determining the expression levels of two or more nucleic acids in a test  
4 sample, wherein the two or more nucleic acids [is] are selected from the group consisting of  
5 Putative cyclin G1 interacting protein, EST (W74293), Fatty-acid -coenzyme A ligase (long-  
6 chain 3), KIAA0220, KIAA0069, Acinus, Translation initiation factor eIF1(A12/SUI1),  
7 Ornithine aminotransferase (gyrate atrophy), Insulin-like growth factor binding protein 1,  
8 Metallothionein-1H, F<sub>1</sub>F<sub>0</sub>-ATPase synthase f subunit, Ring finger protein 5, EST (H73484),  
9 XP-C repair complementing protein, Squalene epoxidase, Microsomal glutathione-S-  
10 transferase 1, Defender against cell death 1, [EST (AA034268),] COPII protein, KIAA0917,  
11 Corticosteroid binding globulin, Calumenin, Ubiquinol-cytochrome c reductase core protein II,  
12 SEC13 (S. cerevisiae)-like 1, EST (R51835), Human chromosome 3p21.1 gene sequence,  
13 [Glutathione-S-transferase-like] EST (AA 441895), Ribonuclease (RNase A family, 4),  
14 Transcription factor Dp-1, MAC30, Cyclin-dependent kinase 4, Multispanning membrane  
15 protein, Splicing factor (arginine/serine-rich 1), Cytochrome c-1, Lactate dehydrogenase-A,  
16 Pyrroline-5-carboxylate synthetase, Glutamate dehydrogenase, Pyruvate dehydrogenase  
17 (lipoamide) beta, Ribosomal protein S6 kinase (90kD, polypeptide 3), Acetyl-coenzyme A  
18 acetyltransferase 2, Proteasome activator subunit 3 (PA28 gamma; Ki), EST (N22016), EST  
19 (AI131502), Activating transcription factor 4, Transforming growth factor-beta type III  
20 receptor, EST (AA283846), EST (AI 310515) and EST (AA805555), wherein the numbers  
21 listed in parentheses is the GenBank accession number; and  
22 (b) comparing the expression levels in the test sample with expression levels  
23 of the same nucleic acids in a control sample, wherein a difference in expression levels  
24 between the test and control samples is an indicator of a toxic response in the test sample.

1                   5. (Amended) The method of claim 1, wherein the group consists of  
2 Putative cyclin G1 interacting protein, EST (W74293), Fatty-acid -coenzyme A ligase (long-  
3 chain 3), KIAA0220, KIAA0069, Acinus, Translation initiation factor eIF1(A12/SUI1),  
4 Ornithine aminotransferase (gyrate atrophy), Insulin-like growth factor binding protein 1,  
5 Metallothionein-1H, F<sub>1</sub>F<sub>0</sub>-ATPase synthase *f* subunit, Ring finger protein 5, EST (H73484),  
6 XP-C repair complementing protein, Squalene epoxidase, Microsomal glutathione-S-  
7 transferase 1, Defender against cell death 1, [EST (AA034268),] COPII protein, KIAA0917,  
8 Corticosteroid binding globulin, Calumenin, Ubiquinol-cytochrome c reductase core protein II,  
9 SEC13 (S. cerevisiae)-like 1, EST (R51835), Human chromosome 3p21.1 gene sequence,  
10 [Glutathione-S-transferase-like] EST (AA 441895), Ribonuclease (RNase A family, 4),  
11 Transcription factor Dp-1, MAC30, Cyclin-dependent kinase 4, Multispanning membrane  
12 protein, Splicing factor (arginine/serine-rich 1), Cytochrome c-1, Lactate dehydrogenase-A,  
13 Pyrroline-5-carboxylate synthetase, Glutamate dehydrogenase, Pyruvate dehydrogenase  
14 (lipoamide) beta, Ribosomal protein S6 kinase (90kD, polypeptide 3), Acetyl-coenzyme A  
15 acetyltransferase 2 and Proteasome activator subunit 3 (PA28 gamma; Ki).

1                   28. (Amended) A method [of conducting expression profiling] identifying  
2 potential toxicants, comprising:

3                   (a) contacting a population of test cells with a test compound, the test cells  
4 harboring at least three reporter constructs, each reporter construct comprising a different  
5 promoter or response element and a heterologous reporter gene operably linked to the promoter  
6 or response element, wherein the promoter or response element is from a gene selected from  
7 the group consisting of Putative cyclin G1 interacting protein, EST (W74293), Fatty-acid -  
8 coenzyme A ligase (long-chain 3), KIAA0220, KIAA0069, Acinus, Translation initiation  
9 factor eIF1(A12/SUI1), Ornithine aminotransferase (gyrate atrophy), Insulin-like growth factor  
10 binding protein 1, Metallothionein-1H, F<sub>1</sub>F<sub>0</sub>-ATPase synthase *f* subunit, Ring finger protein 5,  
11 EST (H73484), XP-C repair complementing protein, Squalene epoxidase, Microsomal  
12 glutathione-S-transferase 1, Defender against cell death 1, [EST (AA034268),] COPII protein,  
13 KIAA0917, Corticosteroid binding globulin, Calumenin, Ubiquinol-cytochrome c reductase  
14 core protein II, SEC13 (S. cerevisiae)-like 1, EST (R51835), Human chromosome 3p21.1 gene

15 sequence, **[Glutathione-S-transferase-like]** EST (AA 441895), Ribonuclease (RNase A  
16 family, 4), Transcription factor Dp-1, MAC30, Cyclin-dependent kinase 4, Multispanning  
17 membrane protein, Splicing factor (arginine/serine-rich 1), Cytochrome c-1, Lactate  
18 dehydrogenase-A, Pyrroline-5-carboxylate synthetase, Glutamate dehydrogenase, Pyruvate  
19 dehydrogenase (lipoamide) beta, Ribosomal protein S6 kinase (90kD, polypeptide 3), Acetyl-  
20 coenzyme A acetyltransferase 2, Proteasome activator subunit 3 (PA28 gamma; Ki), EST  
21 (N22016), EST (AI131502), Activating transcription factor 4, Transforming growth factor-beta  
22 type III receptor, EST (AA283846), EST (AI 310515) and EST (AA805555);

23 whereby if the test compound produces the toxic condition the promoters or  
24 response elements activate the transcription of the reporter gene to produce a detectable signal;

25 **[and]**

26 (b) detecting the level of the detectable signal from the test cells; and  
27 (c) comparing the level of the detectable signal in the test cells with the  
28 level of the detectable signal in a population of control cells under conditions identical to those  
29 for the test cells, except that the control cells are not contacted with the test compound, an  
30 increased level of signal in the test cells indicating that the test compound is a toxicant.

1 *Please add the following new claims:*

2  
3 --29. (New) The method of claim 28, wherein the group consists of Putative  
4 cyclin G1 interacting protein, EST (W74293), Fatty-acid -coenzyme A ligase (long-chain 3),  
5 KIAA0220, KIAA0069, Acinus, Translation initiation factor eIF1(A12/SUI1), Ornithine  
6 aminotransferase (gyrate atrophy), Insulin-like growth factor binding protein 1,  
7 Metallothionein-1H, EST (N22016), EST (AI131502) and Activating Transcription factor 4.

1  
2 30. (New) The method of claim 29, wherein the group consists of Putative  
3 cyclin G1 interacting protein, Fatty-acid -coenzyme A ligase (long-chain 3), Acinus,  
4 Translation initiation factor eIF1(A12/SUI1), Ornithine aminotransferase (gyrate atrophy),  
5 Insulin-like growth factor binding protein 1, Metallothionein-1H and Activating Transcription  
factor 4.--

REMARKS

*OK*  
*U* Claims 1-19 and 28 are currently pending, claims 20-27 having been withdrawn from consideration. New claims 29 and 30 are introduced upon entry of this Amendment.

The paragraph numbering of the Office Action is used in responding to the Examiner's remarks.

I. Amendments to Specification

Certain references in the specification have been amended to list the nucleic acids found to be differentially expressed in response to each of three toxicants (acetaminophen, caffeine and thioacetamide), and which were shown to be differentially expressed by at least two techniques. Nucleic acids satisfying these criteria are listed in Table 1 (see, e.g., page 32, lines 16-21; page 82, lines 12-15 and page 94, lines 18-26). Thus, EST AA805555 has been added to Table I. Support for this change can be found, for example, at page 3, line 2; page 82, lines 12-15; Table 7; and claim 1, line 20. EST (AA034268) has been deleted from Table 1. While this nucleic acid was found to be differentially expressed in response to all three of the model toxicants (see, e.g., page 94, line 18-26), results by quantitative RT-PCR failed to confirm the results obtained using probe arrays (see page 102, Table 12). Other changes to the specification are simply to correct typographical errors.

II. Amendments to Claims

Claim 1 has been amended as recommended by the Examiner to correct the grammatical error. Claim 1, together with claims 1, 5 and 29 have been amended to correctly list all the nucleic acids found to be differentially expressed in response to each of three toxicants (acetaminophen, caffeine and thioacetamide), and which were shown to be differentially expressed by at least two techniques. Support for these changes can be found, for example, at the same locations of the specification as indicated supra for related changes to the specification. Claims 1 and 28 have also been amended to more explicitly state certain utilities associated with the claims. Support for these changes is found throughout the specification,

including, for example, page 17, lines 23-25 and lines 32-33; pages 32-35 and pages 46-50; see also the abstract.

Two new claims that depend upon claim 28 have been added. These claims are supported by claim 28 and Tables 7 and 12, for example.

**III. Drawings**

Paragraph 2. The Examiner notes that certain drawings include informalities. Applicant will provide formal drawings upon notification of allowable subject matter.

**IV. Claim Objections**

Paragraph 3. Claim 1 has been amended to make the grammatical change requested by the Examiner.

**V. Claim Rejection under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph**

Paragraphs 4 and 5. Claims 1-19 and 28 stand rejected for allegedly failing to satisfy the utility requirement pursuant to 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. The Examiner takes the position that the invention is not supported by either a “specific and substantial asserted utility or a well established utility.” (emphasis added). For the reasons that follow, Applicant respectfully disagrees.

The basic considerations for evaluating whether the disclosure in an application satisfies the utility requirement are set forth in the MPEP §§ 706.03(a)(1), 2107, 2107.01 and 2107.02, the Revised Utility Examination Guidelines (published December 16, 1999; referred to herein simply as the “Revised Guidelines”), and in the recently published USPTO Training Materials for Revised Interim Utility Guidelines. The analysis performed to determine whether the utility requirement is satisfied generally is the same for each of these sources, although there is some variation between the sources. The analysis set forth in each of these sources will be applied to the instant invention. It will be shown that regardless of the specific approach, the utility requirement is satisfied.

A. MPEP and Revised Guidelines

The analysis as set forth in the MPEP and the Revised Guidelines is applied first. Under both of these sources, assuming the claims define statutory subject matter, a utility analysis in general constitutes a two-part inquiry. First, after reviewing the entire application, the Examiner is to determine whether the applicant has asserted a particular utility. Secondly, the Examiner is to determine whether any such asserted utility would be credible to one of ordinary skill in the art.

As to the first inquiry, the MPEP more specifically states that the Examiner is to review the specification and claims to determine if the applicant has asserted that the claimed invention “is useful for any particular purpose.” Such a utility is defined as a “specific utility.” MPEP § 706.03(a)(1) (emphases added). The Revised Guidelines state the first inquiry somewhat differently, stating that the Examiner should ascertain whether the applicant has asserted “any specific and substantial utility.” Such an assertion is defined as one that “is useful for any particular practical purpose.” 64 Fed. Reg. p. 71441 (emphases added). Thus, the Revised Guidelines and the MPEP set forth similar criteria for whether the applicant has made an assertion of utility. However, while the MPEP simply refers to a “particular purpose,” the Revised Guidelines also include the requirement of a “practical” purpose. The Revised Guidelines further elaborate that the foregoing standard means utilities other than “‘throw-away,’ ‘insubstantial,’ or ‘nonspecific’ utilities, such as the use of a complex invention as landfill.” 64 Fed. Reg. p. 71441.

As for the second inquiry which addresses the credibility of the assertion, both the Revised Guidelines and the MPEP state that the credibility of the asserted utility is to be assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record. 64 Fed. Reg. p. 71441 and MPEP § 706.03(a)(1). The MPEP elaborates further stating that an “assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.” MPEP § 2107.01. The MPEP further states that in general “an applicant’s assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement.” MPEP § 2107.01.

Thus, based upon the somewhat more detailed standard articulated in the Revised Guidelines, the issue is whether: (1) the instant application asserts a utility that is useful “for any particular practical purpose” and (2) the asserted utility is credible to one of ordinary skill in the art. These inquiries will be addressed in turn.

### 1. Assertion of a Utility

In evaluating whether the application makes an assertion of utility, the Examiner concludes that the presently claimed invention is “drawn to methods of expression profiling.” While the presently claimed methods do involve expression profiling, this is an over generalization of the currently claimed invention. As indicated throughout the specification, the presently claimed invention generally provides methods for conducting expression profiling to detect toxic responses or states and/or identify toxicants (see, e.g., page 17, lines 32-33; see, also, pages 32-35 and pages 46-50). In fact, the pending independent claims as originally worded refer to this specific utility. Original claim 1 concluded that a “difference in expression levels between the test and control samples is an indicator of a toxic response in the test sample.” (emphasis added). Similarly, claim 28 concluded that “an increased level of signal in the test cells indicat[es] that the test compound is a toxicant.” (emphasis added). Thus, while the preamble of the original claims referred to methods of expression profiling, the concluding sentences of the claims (and the specification throughout its entirety) explicitly asserted that the presently claimed invention has utility in identifying a toxic response and/or in identifying potential toxicants.

The value of methods useful for identifying toxic states and identifying potential toxicants is clear. As indicated in the background section, living organisms of all types (including humans) are routinely exposed to a variety of compounds that potentially are toxic and are capable of causing significant harm. The importance of toxicological analyses is evidenced by the fact that assessments of the toxicity of commercial products and pharmaceutical compounds is the focus of two major government agencies (e.g., the Environmental Protection Agency and the Food and Drug Administration). Hence, the capability of the currently claimed methods to identify toxic responses and toxicants means the methods have clear value and utility in a variety of diagnostic applications, in identifying

general or particular toxic states, and in a variety of screening procedures (e.g., screening pharmaceutical candidates to differentiate between non-toxic and toxic compounds) (see, e.g., pages 17-19; pages 32-35; pages 38-39 and pages 46-50). The currently claimed methods can also be performed as cellular assays, thereby avoiding problems associated with toxicological studies performed with animals (see, e.g., page 1, lines 24-33).

Thus, the asserted utility satisfies the requirement that applicant makes an assertion of a "particular purpose" (MPEP) and a "particular practical purpose" (Revised Guidelines). The pending claims specifically refer to the particular purpose of identifying toxic response and identifying potential toxicants. For the reasons just provided, such methods have a clear practical purpose in diagnostic and screening applications, for example, in research, academic and industrial settings. Such utilities cannot fairly be classified as "throw away," "insubstantial," or "nonspecific" utilities.

In view of the foregoing, Applicant submits that the claims as originally worded included an assertion of a particular and practical utility. Nonetheless, to clarify the utility and to advance the prosecution of important subject matter, the preamble to claim 1 has been amended to indicate more explicitly that this claim (and those dependent upon it) has the utility of "detecting a toxic response." Claim 28 has been amended to explicitly state that this claimed method (and the claims depending upon it) has the utility of "identifying potential toxicants."

## 2. Credibility of Assertion

One of ordinary skill in the art would find the foregoing assertions of utility credible for several reasons. First, the methods are based upon the finding that various specific nucleic acids are differentially expressed in cells exposed to a toxic challenge. The nucleic acids identified as being differentially expressed were identified in cells contacted with known toxicants that have been extensively studied by others. More specifically, the nucleic acids listed in the pending claims are differentially expressed in response to three toxicants (acetominophen, caffeine and thioacetamide) known to exert their toxic effects via differing mechanisms (see, e.g., p. 71, line 26 to page 72, line 6). The fact that these nucleic acids are all differentially expressed in response to three toxicants known to act via varying mechanisms

indicates that these particular nucleic acids are important general markers of toxicity (see, e.g., page 32, lines 16-21). It is these specific nucleic acids that are listed in claim 1 and claim 28.

Secondly, the techniques utilized to identify the differentially expressed genes were conducted using established techniques for detecting differentially expressed nucleic acids. The methods utilized included differential display PCR, dot blot analyses and in-situ hybridization (see Example 1) as well as probe arrays and quantitative RT-PCR (see Example 2). Third, confirmation assays were conducted to confirm that the nucleic acids listed in claims 1 and 28 were in fact differentially expressed in response to a toxic challenge. For example, those nucleic acids listed in claims 1 and 28 that were identified by differential display PCR were confirmed using dot blot analyses (see, e.g., page 82, lines 12-15). Nucleic acids identified by probe arrays were confirmed using quantitative RT-PCR (see, e.g., page 94, line 18 to page 95, line 30 and Table 12).

In summary, for all of the foregoing reasons, Applicant submits that the utility requirement has been satisfied since the claims and application include explicit statements that set forth particular practical purposes that one of ordinary skill in the art would deem credible.

B. USPTO Training Materials for Revised Interim Utility Guidelines (“Training Materials”)

As indicated *supra*, the USPTO has recently published training materials to provide more specific and detailed guidance regarding the criteria for satisfying the utility requirement. As demonstrated below, analysis of the present application indicates that under these criteria the utility requirement is also satisfied.

The Training Materials provide a flowchart (see, page 9 of Training Materials) that sets forth a four-part inquiry to determine whether the utility requirement has been satisfied. The four inquiries are as follows: 1) Has the applicant made *any* assertion of utility for the invention?; 2) Does the assertion identify a *specific* utility?; 3) Does the assertion identify a *substantial* utility?; and 4) Is the assertion of specific and substantial utility *credible*? (all emphases in the original). These inquiries will be addressed in turn.

1. Any Assertion of Utility

As set forth in detail above, Applicant made an explicit assertion of utility in the original claims, as well as throughout the specification. Nonetheless, as described *supra*, the pending claims have been amended to clarify and emphasize the asserted utility in the interests of advancing prosecution of important subject matter.

2. Identification of Specific Utility

In defining “specific utility,” the Training Materials contrast a specific utility with a general utility that is applicable to the broad class of invention (see, e.g., pages 5-6 of Training Materials). Thus, one factor to consider when addressing whether a specific utility has been asserted is whether the nucleic acids listed in the pending claims have a property not applicable to nucleic acids generally. Said differently, one consideration is whether the methods require detection of particular nucleic acids.

The present claims do not simply refer to some general characteristic common to all nucleic acids. As described *supra*, the nucleic acids listed in claims 1 and 28 are specific nucleic acids that are differentially expressed in cells that have been exposed to a toxicant. Further, the nucleic acids are ones that are differentially expressed in response to a toxic challenge from three different toxicants that exert their cytotoxic effect according to different mechanisms. Thus, these particular enumerated nucleic acids have a property not applicable to nucleic acids generally, namely they function as cytotoxic markers, a characteristic that is not common to the general class of nucleic acids. As such, the nucleic acids have a specific utility rather than a general utility.

Example 9 of the Training Materials discusses claims directed towards DNA fragments. The definition section and Example 9 of the Training Materials indicate that simply stating that nucleic acid fragments have some general utility as probes to identify full length genes does not constitute a specific utility, as this utility is common to all nucleic acid fragments from cDNAs. That is not the situation with the present claims because the nucleic acids listed in the pending claims serve as markers of cytotoxicity.

The number of nucleic acids listed in the present claims is relatively small and thus is consistent with assertion of a specific utility. Furthermore, the present claims refer to

very specific nucleic acids, and these are a small subset of all of the differentially expressed genes identified in the instant application (see Appendix A). As stated supra, the nucleic acids listed in the claims are limited to those that were differentially expressed in cells exposed to each of three toxicants. Differential expression results for these particular nucleic acids was also confirmed through the use of different assay techniques.

Other considerations include whether methods associated with identifying or monitoring a condition refer to conditions generally or to particular conditions. The pending claims reciting to conditions refer to particular, rather than general, conditions (see, claim 1 and claims dependent thereon). In particular, certain of the pending claims refer specifically to methods that can be useful in identifying toxic conditions, rather than simply referring to generic conditions. Furthermore, the methods are directed towards a well-known problem/condition for which the art recognizes a need for additional methods.

In view of foregoing, Applicant submits that the presently claimed invention does set forth a specific utility.

### 3. Assertion of Substantial Utility

According to the definition in the Training Materials, a “substantial utility” is one that has a “real world use.” It is a utility that does not require further research to identify a real world context. Furthermore, consistent with the Revised Guidelines, the utility cannot be a “throw away” utility (see, pages 6-7 of the Training Materials, definition section).

The definition section also provides specific examples of methods that lack a substantial utility. One such example that is provided is a method of assaying for or identifying a material that itself has no “specific and/or substantial utility” (page 6 of Training Materials). The Examiner appears to view the present claims as falling within this category, as he states that the specification fails to state specific and substantial utilities for two or more nucleic acids in a test sample as selected from the list in the pending claims. However, this position ignores the fact that the claims and the specification clearly state that the nucleic acids recited in the claims are those identified as being differentially expressed in response to a toxic insult. Additionally, the nucleic acids are ones that are differentially expressed in response to

several diverse toxic insults. Thus, the enumerated nucleic acids do have a specific and substantial utility as markers of cytotoxicity.

The Examiner states that the utility of the methods is limited to research methods and that such utility falls short of satisfying the requirement for a real world application. Applicant disagrees that the utility of the present invention is so limited and submits that the pending claims do have a real world application. As set forth *supra*, methods for identifying toxic states and potential toxicants have utility in a wide variety of real world applications. Such applications include, for example, use in the detection of toxic responses, screening compounds to identify those with potentially toxic characteristics, the identification of antidotes, and diagnostic applications (e.g., in identifying individuals suffering from exposure to toxicants). Each of the methods can be utilized directly in such applications without any further research.

The Training Materials specifically state that an "assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease or condition would also define a 'real world' context of use." The current claims are examples of such claims. The assays have been correlated with a particular condition. Specifically, as noted repeatedly above, the nucleic acids listed in the pending claims are ones that have been shown to be markers for cytotoxicity because they are differentially expressed in response to exposure to toxicants acting by different mechanisms. As also stated above, the methods refer to a particular condition, namely a toxic state. Thus, under this specific example from the Training Materials, the pending claims satisfy the requirements for a real world use.

In view of these real world applications, it is clear that the asserted utilities constitute substantially more than mere "throw away" utilities.

For all of the foregoing reasons, it is submitted that the requirement for assertion of a substantial utility is satisfied.

#### 4. Credibility of Asserted Specific and Substantial Utility

The standard for a "credible utility" is the same as that set forth in the MPEP. In particular an assertion of utility is to be deemed credible unless (A) the logic underlying the

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assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.” Credibility is also to be evaluated from the standpoint of one of ordinary skill in the art. For all of the reasons set forth above on credibility, one of ordinary skill in the art would consider the asserted utility credible.

Thus, regardless of the particular analysis, in particular whether utility is evaluated pursuant to the MPEP, the Revised Guidelines and/or the Training Materials, the instant application satisfies the utility standard. Additionally, as the MPEP makes clear, where an assertion of utility has been made, it should be presumed that the utility standard is satisfied. Consequently, it is respectfully submitted that the rejection for lack of utility be withdrawn.

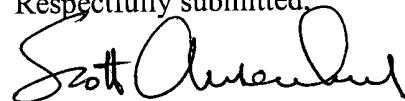
VI. Information Disclosure Statement

It is noted that the Office Action did not have the Information Disclosure Statement (Form 1449) submitted on June 6, 2000, attached to it. Applicant's respectfully request that the references cited in the disclosure statement be expressly considered by the Examiner and be made of record in the instant case.

CONCLUSION

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



Scott L. Ausenhus  
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